DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2703n

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-66

June 1, 1999

Ilhan M. Bilgutay, President
Pace Tech Inc.
510 Garden Avenue North
Clearwater, Florida 33755

Dear Mr. Bilgutay:

We are writing to you because on April 1,2,5, & 6, 1999 FDA Investigator Christine M. Humphrey collected information that revealed serious regulatory problems involving the Minipack 911 (compact) and the Vitalmax 4000 stationary patient monitors (Class II), which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform to the Quality System (QS) regulations for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section **501(h)** of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

GMP REGULATIONS

1) Failure to establish and maintain procedures for implementing corrective and preventive actions to ensure that investigations of device failures are adequately conducted and documented, as required by 21 CFR 820.100, e.g., work orders/reports reviewed

found 17 of 34 for all products and 4 of 6 for the Minipack 911 without failure investigations having been completed and/or no reports documenting the reason no investigation was conducted (FDA 483, Item #1).

2) Failure to establish, implement and maintain procedures to control product that does not conform to specifications, as required by 21 CFR 820.90, e.g., 13 of 34 work orders for monitors failing final NIPB QC testing and of the 13 failures, 11 failed a second time (FDA 483, Item #4). 17 of 40 work orders for service reports revealed inaccurate or incomplete failure codes (FDA 483, Item #6).

3) Failure to establish, conduct and document planned and periodic audits of the quality assurance program, as required by 21 CFR 820.22, e.g., Design controls, Corrective and Preventive Actions, Purchasing Controls, Change Control, Training, Device Master and History Records, and Installation and Servicing of installed devices (FDA 483, Item #9).

4) Failure to establish, maintain and implement procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198, e.g., there is no complaint log, oral complaints are not always documented, failure investigations are not always documented, there is no documentation that complaints are evaluated for MDR, there is no trend analysis conducted of complaints, the "Customer Complaint" form, CPP001, is not used (FDA 483, Item #2); and service reports are not evaluated or analyzed pursuant to written procedures (FDA Item #5).

5) Failure to establish and maintain a Device Master Record (DMR) for the Minipack 911, as required by 21 CFR 820.181, e.g., there is no DMR that contains or references process specifications, test methods, and quality assurance procedures (FDA 483, Item #3).

6) Failure to validate the packaging process for the Minipack 911 and the Vitalmax 4000 devices, as required 21 CFR 820.75, (FDA 483, Item #10).

Your written responses dated April 19, 1999 to the Inspectional Observations (FDA 483) issued to you on April 6, 1999 were found to be inadequate for the following reasons:

- Your responses fail to demonstrate the implementation of the procedures and forms for numerous complaints and failures previously reported.

- There is a memo dated July 10, 1997 summarizing a failure investigation, which was not provided to the investigator during the inspection, and there is no raw data supporting the conclusions and the corrective and preventive actions taken.

- There is no documented trend analyses or updates to the DMR for the Minipack 911 provided in the response.

- There are no records provided for training that has been conducted identifying the individuals who received the training.

- There are no protocols provided describing the validations that will be conducted and what parameters will be followed and tested.

- There are no design control procedures provided that you intend to follow.

- There are no procedures covering quality audits including schedules of audits to be conducted.

Several of the listed inspectional observations including FDA 483, Item #s 1, 4, 5, & 7 were listed during previous inspections of your firm. Corrections for these observations were promised, however, they were determined not to have been corrected.

Your response to FDA 483, Item #8 was found to be adequate.

DESIGN CONTROL REGULATIONS (FDA 483, Item #8)

1) Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a), e.g., there are no design control procedures for the design change made to the Vitalmax 4000 series monitor under SCR #980800.

2) Failure to establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation, as required by 21 CFR

820.30(b), e.g., there is no design plan for the change made to the Vitalmax 4000 series monitor under SCR #980800.

3) Failure to establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by 21 CFR 820.30(c), e.g., design input requirements have not been established for the change made to the Vitalmax 4000 series monitor under SCR #980800.

4) Failure to establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements, as required by 21 CFR 820.30(d), e.g., there are no written procedures covering design output requirements for the change made to the Vitalmax 4000 series monitor under SCR #980800.

5) Failure to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development, as required by 21 CFR 820.30(e), e.g., there are no written procedures covering design review for the change made to the Vitalmax 4000 series monitor under SCR #980800.

6) Failure to establish and maintain procedures for verifying the device design, as required by 21 CFR 820.30(f), e.g., there was no written procedure for the testing conducted for the change made to the Vitalmax 4000 series monitor under SCR #980800.

7) Failure to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g), e.g., there are no written procedures for validation for the change made to the Vitalmax 4000 series monitor under SCR #980800.

8) Failure to establish and maintain procedures to ensure that the device design is correctly translated into production specifications, as required by 21 CFR 820. 30(h), e.g., there were no written procedures for design transfer for the change made to the Vitalmax 4000 series monitor under SCR #980800.

9) Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i), e.g., there were no adequate, written procedures for the design

change made to the Vitalmax 4000 series monitor under SCR #980800.

10) Failure to establish and maintain a design history file for each type of device, as required by 21 CFR 820.30(j), e.g., there was no design history file for the change made to the Vitalmax 4000 series monitor under SCR #980800.

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contract, and to resume marketing clearance, and export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device QS regulation/GMPs (21 CFR Part 820). You should also submit a copy of the consultant's report, and certification by your firm's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- Date and certification of initial audit by consultant and firm (to be conducted within 30 calendar days of the receipt of this letter).

- Subsequent certifications by consultant and firm - show actual dates.

- Monthly reports and timeline of progress to achieve compliance to be submitted by the last day of each month.

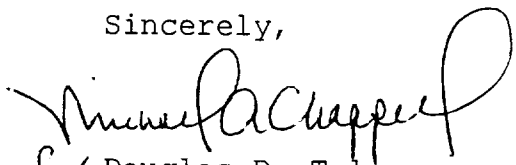
- Final certification to be submitted no later than November 30, 1999.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407)475-4728.

Sincerely,



for Douglas D. Tolen
Director, Florida District